

HERBAL COUGH DROP- menthol lozenge

TopCo Associates

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Menthol 4.8 mg

Active ingredient (in each drop)

Menthol 4.8 mg

Purpose

Cough suppressant / Oral anesthetic

Uses temporarily relieves:

- cough as may occur with a cold or inhaled irritants
- minor sore throat

Warnings

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly. These symptoms may be serious.

Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus)

Stop use and ask doctor if

- cough persists for more than 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- sore throat is severe, or irritation, pain or redness lasts or worsens
- sore mouth does not improve in 7 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Directions

adults and children 6 years and over - allow 2 drops to dissolve slowly in mouth, one at a time. May be repeated every 2 hours as necessary or as directed by a doctor.

children under 6 years - ask a doctor

Other information

- 17 calories per drop

Inactive ingredients: Caramel (color), corn starch, glucose syrup, herbal extract blend (Elderflower, Horehound, Hyssop, Lemon Balm, Linden Flower, Marshmallow Root, Peppermint, Sage, Thyme, Wild Thyme), medium chain triglycerides, natural flavors,

soybean oil, sucrose, water.

Questions? Or to report an adverse event call 1-888-423-0139.



HERBAL COUGH DROP

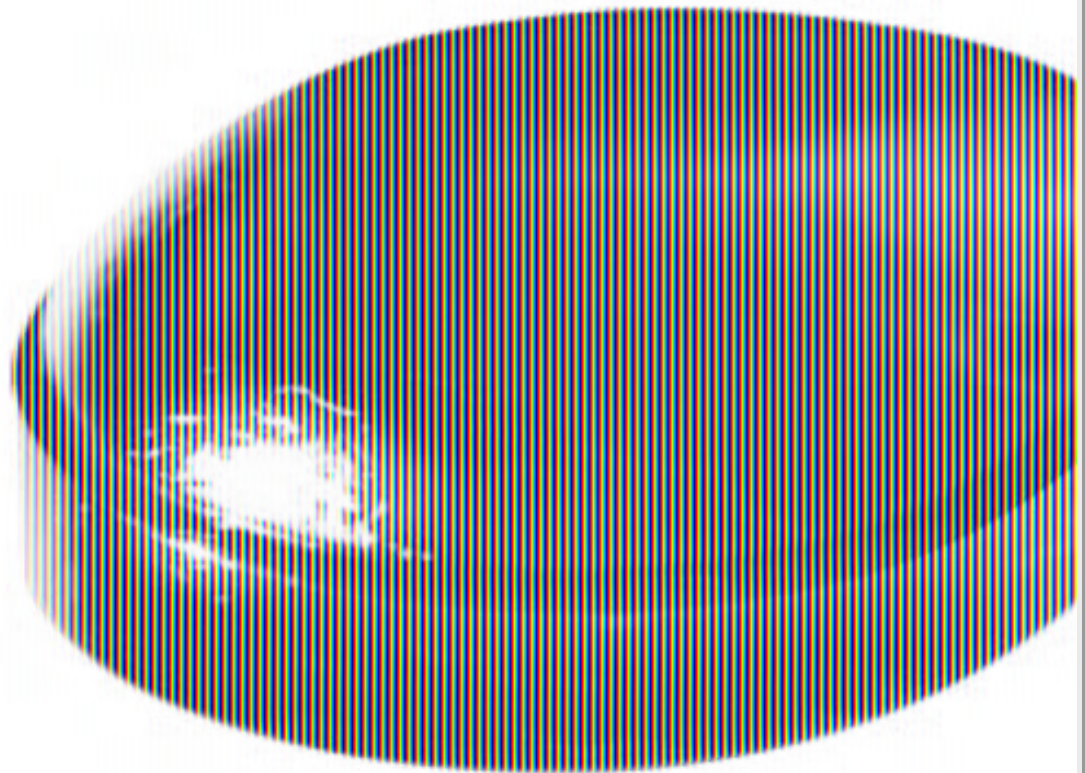
menthol lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-834
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	4.8 mg
Inactive Ingredients			
Ingredient Name		Strength	
WATER (UNII: 059QF0KO0R)			
Product Characteristics			

Color	brown	Score	no score
Shape	OVAL	Size	18mm
Flavor	PEPPERMINT	Imprint Code	B
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-834-21	21 in 1 BAG; Type 0: Not a Combination Product	09/26/2018	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/26/2018	

Labeler - TopCo Associates (006935977)

Registrant - Bestco Inc. (002149136)

Establishment

Name	Address	ID/FEI	Business Operations
Bestco Inc.		002149136	manufacture(36800-834)

Revised: 11/2021

TopCo Associates